REMARKS

Amendments to Claims

Applicants have amended claim 1 such that it recites a method requiring drug delivery for a period of greater than 48 hours, rather than a month. Support for this may be found in the application at page 13, lines 8-22, page 4, line 10, and page 30 line 11 and page 46 line 13, and page 47 line 32 where the period of drug delivery is taught.

Additionally, claim 1 has been amended to recite a "biodegradable synthetic controlled release carrier media material". Support for this may be found in the application at pages 25-31.

Applicants have written new claims 26-28 that depend from claim 1, to recite a drug delivery unit of specific dimensions. Support for these limitations may be found in the application, for example, at page 42, lines 20-25.

Additionally, new claim 29, that also depends from claim 1, recites a method wherein the therapeutic agent is to be delivered into said inner ear in microgram or nanogram quantities. Support for this limitation may be found in the application, for example, at page 8, lines 17-20.

Applicants have written new claim 30 and dependent claims 31-34 such that they recite a "biodegradable synthetic controlled release carrier media material" and recite "placing said drug delivery unit substantially within said round window niche." Support for such substantial placement may be found in the application at page 42, lines 22-25, where dimensions of the drug delivery unit are taught. Specifically, it is taught that the drug delivery unit may have a length of about 0.5 – 20 mm and a diameter of about 0.5 – 4 mm. Such dimensions produce a drug delivery unit having a volume of between 0.098 mm^3 and 251 mm^3. Since it is well known that the volume of the round window niche in humans[1] is between about 34 to 68 mm^3, it follows that a drug delivery device of the invention, depending on its volume, may be placed completely or substantially or partially within the round window niche.

[1] Nomura, Y. "Otological Significance of the round window" Advances in Oto-rhino-laryngology Vol. 33 Pfaltz (ed) Krager, Basel, 1984

Additionally, claim 30 and dependent claims 31-34, recite delivery for a period of greater than 48 hours, support for which can be found as for amended claim 1.

New claims 31-34, which depend from claim 30, recite a drug delivery unit having specific dimensions or quantities of therapeutic agent delivery. Support for these limitations may be found in the application as cited for new claims 26-29 above.

Applicants have written new claim 35 and dependent claims 36-39, such that they particularly recite a "biodegradable synthetic controlled release carrier media material" and recite "placing said drug delivery unit completely within said round window niche." Support for this limitation may be found in the application, for example, at page 23, line 15, page 42, line 14, at page 43, line 12, and at page 44, line 14. Note that at page 43, line 26 et seq., the Applicants emphasize the particular novelty of placing the drug delivery unit in the round window niche.

New claims 36-39, which depend from claim 35, recite a drug delivery unit having specific dimensions (claims 36-38) or quantities of therapeutic agent delivery (claim 39). Support for these limitations may be found in the application as cited for claims 26-29 above.

New claim 40, and dependent claims 41-42, recite a drug delivery apparatus comprising: an elongate member with a drug delivery unit secured at one end. These claims recite placing the drug delivery unit substantially or completely within said round window niche, and are supported at the same places in the application as discussed above for claim 30 (for "substantially") and claim 35 (for "completely").

New claim 41, which depends from claim 40, recites a drug delivery unit of specific dimensions. Support for this limitation may be found in the application as cited for claim 28 above.

New claim 42, which depends from claim 40, recites a drug delivery unit wherein the elongate member is comprised of at least one electrically conductive material. Support for this limitation may be found in the application at for example, page 16, lines 16-21 and Figure 6.

Applicants have written new claim 43 and dependent claims 44-47, such that they are essentially the same as claim 1, but are not limited to a biodegradable synthetic controlled release carrier media material. The claim recites a method requiring drug

delivery for over a period of great than 48 hours. Support for this limitation in the application is the same as described above for claim 1.

New claims 44-47, which depend from claim 43, recite a drug delivery unit having specific dimensions or quantities of therapeutic agent delivery. Support for these limitations may be found in the application as cited for claims 26-29 above.

Applicants have written new claim 48 that depends from claim 1 and recites an "injectable" biodegradable synthetic controlled release carrier media. Support for this may be found in the application at page 43, lines 29-35, where methods of insertion are taught, also page 7, lines 9-13; page 29, lines 23-27; and page 45 lines 8-15.

Rejections Under 35 U.S.C. §103

Claim 1, 3-4, 6, 20, 22-25 are rejected under 35 U.S.C. §103(a) as being unpatentable over Manning et. al. (WO 97/38698) in view of Peterson (U.S. Patent No. 4,472,394). Claims 1-2, 4-5, 20-21 are also rejected under 35 U.S.C. §103(a) as being unpatentable over Manning in view of Peterson and further in view of Husmann et al. (Hearing Research, Round window administration of gentamicin: a new method for the study of ototoxicity of cochlear hair cells).

The legal standards for establishing a prima face case of obviousness is well-established and clearly set out in the MPEP at 706.02(j).

> "To establish a prima face case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation ...to modify or combine reference teachings. Second, there must be **a reasonable expectation of success**. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not [be] based on applicant's disclosure. In re Vaeck, 947 F.2d 488; 20 USPQ2d 1438 (Fed. Cir. 1991)."

No Reasonable Expectation of Success Could Have Been Predicted by Combining the Manning and Peterson References.

To place the application in better condition for allowance, claim 1 has been amended to recite a "biodegradable" form of synthetic controlled release carrier material.

In view of the presently amended claims, Applicants assert that at the time the instant application was filed, a person of ordinary skill in the art would not have had a reasonable expectation of practicing the claimed invention through a combination of the Manning and Peterson references.

Specifically, one of skill in the art would not reasonably expect to successfully make or use a biodegradable synthetic controlled release carrier media material for delivery of a therapeutic agent over a period of greater than 48 hours by combining the disclosure of Peterson (a non-biodegradable silastic silicone rubber implant) with the compositions described by Manning (a biocompatable Hyaluronic acid implant that releases substantially all of the loaded drug within 24 hours into the middle ear. See page 10, lines 1-13 of the Manning patent). The silastic implant cannot easily be adapted to be biodegradable, and the hylauronic acid material cannot be easily adapted toe release drug for a period of greater than 48 hours. Since there is no reasonable expectation of success, the claimed invention cannot be obvious in view of these two references, and the applicants respectfully request that the rejections be withdrawn.

The Examiner further rejects claims 1-2, 4-5 and 20-21 under 35 U.S.C. §103(a) as being unpatentable over Manning in view of Peterson and further in view of Husmann. In light of newly amended claim 1 and the remarks above, this second basis for rejection is moot. Applicants thus respectfully request that this rejection under 35 USC §103(a) also be withdrawn.

CONCLUSION

In light of the above amendments and remarks, Applicants submit that the present application is fully in condition for allowance, and request that the Examiner withdraw the outstanding rejections. Early notice to that effect is earnestly solicited.

If the Examiner contemplates other action, or if a telephone conference would expedite allowance of the claims, Applicants invite the Examiner to contact Applicants' Attorney at (408) 864-7435.

The appropriate fee is attached or authorized. If the Commissioner determines that an additional fee is necessary, the Commissioner is hereby authorized to charge any additional fees associated with this communication or credit any overpayment to Deposit Account No. **50-1953. A duplicate copy of this communication is enclosed.**

If there are any questions regarding the above, the Examiner is invited to call the undersigned at 408-864-7435.

Respectfully submitted,

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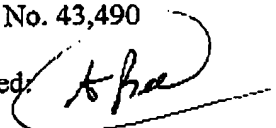
Signed: 

Dated: 5/20/03

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Signed: 

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